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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,290	08/21/2001	Rosana Kapeller-Libermann	MNI-186	8801

7590 05/05/2005

Intellectual Property Group
MILLENNIUM PHARMACEUTICALS INC.
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CAMBRIDGE, MA 02139

EXAMINER	
NASHED, NASHAAT T	
ART UNIT	**PAPER NUMBER**
1652	

DATE MAILED: 05/05/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/935,290	KAPELLER-LIBERMANN ET AL.	
	Examiner	Art Unit	
	Nashaat T. Nashed, Ph. D.	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 6-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2 and 6-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/13/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 13, 2005 has been entered.

The application has been amended as requested in the communication filed April 13, 2005. Accordingly, claims 6, 7, and 8 have been amended, and claim 4 has been canceled.

Claims 1, 2, and 6-11 are pending and under consideration.

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 2, and 6-11 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well-established utility, see previous Office action mailed January 21, 2004, September 15, 2004, and February 28, 2005. For the convenience of the applicant, the rejection is stated below.

Applicants disclose a nucleic acid sequence of SEQ ID NO: 1 (SEQ ID NO: 3 is the coding region of SEQ ID NO: 1) comprising an open reading frame encoding the amino acid sequence of SEQ ID NO: 2. The application indicates that the polypeptide of SEQ ID NO: 2 is sought to be an acyltransferase based on the observation of reasonable sequence homology between the amino acid sequence of SEQ ID NO: 2 and a known acyltransferase in the prior art. While the acyltransferase is accepted as a plausible and credible asserted utility, it is not a specific or substantial utility. One of ordinary skill in the art would not know which acyl group is being transferred and to what acceptor. Since human produces many acyltransferases for many purposes included those referred to in the Background section of the specification, each acyltransferase is expected to have a specific substrates and function. The specification describes non-specific utilities for the protein, nucleic acid, and antibodies. The nucleic acid is said to be used in a method to detect a human gene and to recombinantly make the polypeptide of SEQ ID NO: 2 which neither the gene nor the polypeptide are associated with a specific use or a disease. The mere fact that the polypeptides disclosed in the specification is called 56919, a novel human acyltransferase is indicative that the applicants have no idea about the specific utility of the protein of SEQ ID NO: 2 or the nucleic acid sequences of SEQ ID NO's: 1 and 3 at the time they filed their application. It appears that the main utility of the polypeptide and nucleic acid is to carry out further

research to identify the biological function and possible diseases associated with said function. Substantial utility defines a "real world" use. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utility. Thus, the claimed invention has no specific or substantial asserted utility.

In response to the above rejection, applicants argue that the specification sets forth use of the described compositions in a method for diagnostics and identification of therapeutics for disorders including, for example metabolic disorders, and that one of ordinary skill in the art would have recognized a well-established utility. They further argue that the specification as filed in conjunction with the knowledge of those skilled in the art would equip one to readily demonstrate the acyltransferase activity.

Applicants' arguments filed March 13, 2005 have been fully considered, but they are found unpersuasive. Indeed, the specification sets forth use of the described compositions in a method for diagnostics and identification of therapeutics for disorders including, for example metabolic disorders, but it has not identified a single disease or disorder, including a specific metabolic disorder, which the claimed nucleic acid or the protein product encoded by the claimed nucleic acid can be diagnosed or useful in identifying potential drugs for the treatment of said disease or disorder. The fact that the nucleic acid sequences of SEQ ID NO's: 1 and 3 and the amino acid sequence of SEQ ID NO: 2 are not previously known in the prior art, one of ordinary skill in the art would have recognized that neither the nucleic acid sequences of SEQ ID NO's: 1 and 3, or the amino acid sequence of SEQ ID NO: 2 have any well-established utility. Applicants point to the specification at page 10 as an example of the many specific and substantial utility. Page 10 of the specification from line 9-38 is nothing more than a wish list of utilities and possible uses for the polypeptide and nucleic acid of the claimed invention. At page 10, second paragraph, there are eight possible biological activities for the polypeptide of SEQ ID NO: 2, and there are in the following paragraph. While it may be possible for one of ordinary skill in the art to demonstrate the acyltransferase activity of the protein of SEQ ID NO: 2, the application must contain an asserted specific or substantial utility at the time the application was filed. Since the application failed to identify a specific or substantial utility at the time it was filed, the claims remain rejected. Also, applicants suggest the example 5 and the results in Figure 10 show that the polypeptide is upregulated, which the examiner presumes the expression of the polypeptide of SEQ ID NO: 2 is increases. The specification, however, does not link or discuss the biological significance or implication of such an increase and its relationship to diseased states. The major conclusion of example 5 is that the result is consistent with that the gene encoding SEQ ID NO: 2 plays a key role in regulation of triglyceride biosynthesis. It is possible that this is the case, but the exact role is not stated in the specification, and the result seems to be an invitation to further experimentation to identify the role, and may be its relationship to a diseased state. Finally, applicants allege that the utility rejection is improper because the examiner allegedly did not follow the steps in MPEP 2107 (II)(C). Indeed, the examiner has followed the teaching of

MPEP (see the restated rejection above). The examiner has accepted the asserted utility of an acyltransferase as required because he had no evidence to doubt such an assertion. The specification, however, does not teach a single use or function for the asserted utility. Applicants assert that one of ordinary skill in the art would know what to do with it because there are many known acyltransferases and the use of the polypeptide of SEQ ID NO: 2 should have the same uses. The examiner disagrees for reasons of record, and refers the applicant to the prior Office actions and the restated rejection above. It is true there are many known well-characterized acyltransferases and each of which has a specific chemical utility and biological function that is different from the others. Thus, the claims remain rejected.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 2, and 6-11 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention, see previous Office action mailed January 21, 2004, September 15, 2004, and February 28, 2005.

No claim is allowed.

This is a RCE of applicant's earlier Application No. 09/935,290. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Nashaat T. Nashed, Ph. D.
Primary Examiner
Art Unit 1652